JAN 22 2010

K093950 1/1

# 510(K) SUMMARY
# OF SAFETY AND EFFECTIVENESS

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CRF 807, this information serves as a Summary of Safety and Effectiveness for the use of the BIOFOAM® Bone Wedge.

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| Submitted By: | Wright Medical Technology, Inc. |
| Date: | January 22, 2010 |
| Contact Person: | Kellen Hills<br>Regulatory Affairs Specialist |
| Proprietary Name: | **BIOFOAM® Bone Wedge** |
| Common Name: | Bone Wedge |
| Classification Name and Reference: | 21 CFR 888.3030 - Single/multiple component metallic bone fixation appliances and accessories – Class II |
| Device Product Code and Panel Code: | Orthopedics/87/HRS/HWC |

## DEVICE INFORMATION

### A. INTENDED USE

The BIOFOAM® Bone Wedge is intended to be used for internal bone fixation for bone fractures, fusions, or osteotomies in the ankle and foot, such as:

- Opening wedge osteotomies of Hallux Valgus
- Evans lengthening osteotomies
- Metatarsal/cuneiform arthrodesis

This device is intended for use with ancillary fixation.

The BIOFOAM® Bone Wedge is not intended for use in the spine.

### B. DEVICE DESCRIPTION

The BIOFOAM® Bone Wedge is a titanium metal foam wedge used for angular correction of small bones in the ankle and foot. It is offered with varying widths and thicknesses to accommodate a variety of small bone applications.

### C. SUBSTANTIAL EQUIVALENCE INFORMATION

The design features of the BIOFOAM® Bone Wedge are substantially equivalent to the design features of the predicate identified in this 510(k) submission. The safety and effectiveness of the BIOFOAM® Bone Wedge are adequately supported by the substantial equivalence information, materials information, and analysis data provided within this 510(k).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

JAN 22 2010

Wright Medical Technology, Inc.
% Mr. Kellen Hills
5677 Airline Road
Arlington, Tennessee 38002

Re: K093950
Trade/Device Name: BIOFOAM Bone Wedge
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: HRS, HWC
Dated: December 21, 2009
Received: December 23, 2009

Dear Mr. Hills:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Indications for Use

510(k) Number (if known): K093950

Device Name: BIOFOAM® Bone Wedge

Indications For Use:

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Prescription Use **xxx** AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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(Division Sign-Off)
Division of Surgical Orthopedic,
and Restorative Devices

510(k) Number K093950

Concurrence of CDRH, Office of Device Evaluation (ODE)